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## Bayer MaterialScience Texin® 5250, Thermoplastic Polyurethane, Polyeth based, Medical

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This grade is in chemical compliance with 21 CFR 177.1680 (Polyurethane Resins) and 177.2600 (Rubber article: intended for repeated use) subject to the limitations of this regulation and any other regulations.

It is the responsibility of the medical device, biological product, or pharmaceutical manufacturer (*Manufacturer*) to determine the suitability of all components and raw materials, including the Bayer Corporation product identified in this electronic database, used in its final product in order to ensure safety and compliance with FDA regulations. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact and/or storage of solutions/liquids, including, without limitation, blood, medication, or other bodily fluids.

Under no circumstances, however, may the Bayer Corporation product be used in any cosmetic, reconstructive or reproductive implant applications. No Bayer Corporation resin be used in any other bodily implant applications or any applications involving contact with or storage of human tissue, blood, or bodily fluids for greater than 30 days, based on FDA modified ISO 10993, Part 1 *Biological Evaluation of Medical Devices* tests. Furthermore, for aromatic of Texin TPU resins, longer term uses are not permissible because possible hydrolysis of solid urethane may produce aromatic amines, such as methyldianiline (MDA).

The suitability of a Bayer product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stress, or external loads. It is the responsibility of the Manufacturer to evaluate its final product against actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single use medical devices made from Bayer products are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

If you have any questions on the regulatory status of any of Bayer Corporation products identified in this electronic database, please contact your local Bayer Corporation representative or the Bayer Corporation Regulatory Affairs Manager in the Health, Environment, and Safety Department in Pittsburgh, Pa.

**Biocompatibility Information**

The medical grades of the Bayer Corporation products identified in this electronic database have met the FDA modified ISO 10993, Part 1 *Biological Evaluation of Medical Devices* tests with human tissue contact time of 30 days or less. ONLY THESE PRODUCTS MAY BE CONSIDERED AS CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY. No *medical grade* products will be available for sale until successful completion of testing.

Reground resins must not be used in medical applications requiring biocompatibility.

**Sterilization Information**

The sterilization method and the number of sterilization cycles a part made from a Bayer Corporation product identified in this electronic database can vary depending upon the type and grade of resin, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual requirements and must adequately advise and warn purchasers and users thereof.

Parts molded or extruded from Texin TPU resins are sterilizable using ethylene oxide, radiation, or dry heat. Steam autoclaving and boiling water techr possible only with selected aliphatic grades of Texin. These sterilization methods must not be used with aromatic grades of Texin resins because possible hydrolysis of solid urethane may produce aromatic amines, such as methylene dianiline (MDA).

Information provided by Bayer Corporation, Plastics Division

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Physical Properties	Metric	English	Con
Density	<u>1.15 g/cc</u>	0.0415 lb/in <sup>3</sup>	ASTI
Linear Mold Shrinkage	<u>0.008 cm/cm</u>	0.008 in/in	ASTI
Linear Mold Shrinkage, Transverse	<u>0.008 cm/cm</u>	0.008 in/in	ASTI

#### Mechanical Properties

Hardness, Shore D	50	50	ASTM
Tensile Strength, Ultimate	<u>41 MPa</u>	5950 psi	ASTI
Tensile Strength, Yield	<u>12 MPa</u>	1740 psi	50% Elongation; ASTI
Elongation at Break	400 %	400 %	ASTI
Flexural Modulus	<u>0.11 GPa</u>	16 ksi	ASTI
Resilience	35	35	% Bayshore Resilience; ASTM
Tear Strength	<u>130 kN/m</u>	742 pli	Die C; ASTI
Taber Abrasion, mg/1000 Cycles	75	75	H-18 Wheel, 1000 g load, ASTM
Compression Set	15 %	15 %	22 hours at RT (Postcured); ASTM
Compression Set, Elevated Temperature	40 %	40 %	22 hours at 158°F (Postcured); ASTM

#### Thermal Properties

Vicat Softening Point	<u>128 °C</u>	262 °F	Rate A; ASTM
Brittleness Temperature	<u>Max -68 °C</u>	Max -90.4 °F	ASTI
Glass Temperature	<u>-27 °C</u>	-16.6 °F	

#### Processing Properties

Processing Temperature	<u>205 °C</u>	401 °F	Ideal melt temp.
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## Bayer MaterialScience Texin® 5286, Thermoplastic Polyurethane, Polyeth based, Medical

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Under no circumstances, however, may the Bayer Corporation product be used in any cosmetic, reconstructive or reproductive implant applications. No Bayer Corporation resin be used in any other bodily implant applications or any applications involving contact with or storage of human tissue, blood or bodily fluids for greater than 30 days, based on FDA modified ISO 10993, Part 1 *Biological Evaluation of Medical Devices* tests. Furthermore, for aromatic of Texin TPU resins, longer term uses are not permissible because possible hydrolysis of solid urethane may produce aromatic amines, such as methyldianiline (MDA).

The suitability of a Bayer product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stress, or external loads. It is the responsibility of the Manufacturer to evaluate its final product in actual end-use requirements and to adequately advise and warn purchasers and users thereof.

Single use medical devices made from Bayer products are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

If you have any questions on the regulatory status of any of Bayer Corporation products identified in this electronic database, please contact your local Bayer Corporation representative or the Bayer Corporation Regulatory Affairs Manager in the Health, Environment, and Safety Department in Pittsburgh, Pa.

**Biocompatibility Information**

The medical grades of the Bayer Corporation products identified in this electronic database have met the FDA modified ISO 10993, Part 1 *Biological Evaluation of Medical Devices* tests with human tissue contact time of 30 days or less. ONLY THESE PRODUCTS MAY BE CONSIDERED AS CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY. No medical grade products will be available for sale until successful completion of testing.

Regrind resins must not be used in medical applications requiring biocompatibility.

**Sterilization Information**

The sterilization method and the number of sterilization cycles a part made from a Bayer Corporation product identified in this electronic database can vary depending upon the type and grade of resin, part design, processing parameters, sterilization temperature, and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual requirements and must adequately advise and warn purchasers and users thereof.

Parts molded or extruded from Texin TPU resins are sterilizable using ethylene oxide, radiation, or dry heat. Steam autoclaving and boiling water technique are possible only with selected aliphatic grades of Texin. These sterilization methods must not be used with aromatic grades of Texin resins because possible hydrolysis of solid urethane may produce aromatic amines, such as methylene dianiline (MDA).

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Physical Properties	Metric	English	Con
Density	<u>1.12 g/cc</u>	0.0405 lb/in <sup>3</sup>	ASTI
Linear Mold Shrinkage	<u>0.008 cm/cm</u>	0.008 in/in	ASTI
Linear Mold Shrinkage, Transverse	<u>0.008 cm/cm</u>	0.008 in/in	ASTI

#### Mechanical Properties

Hardness, Shore A	86	86	ASTM
Tensile Strength, Ultimate	<u>38 MPa</u>	5510 psi	ASTI
Tensile Strength, Yield	<u>4.8 MPa</u>	696 psi	50% Elongation; ASTI
Elongation at Break	500 %	500 %	ASTI
Flexural Modulus	<u>0.027 GPa</u>	3.92 ksi	ASTI
Resilience	45	45	% Bayshore Resilience; ASTM
Tear Strength	<u>90 kN/m</u>	514 pli	Die C; ASTI
Taber Abrasion, mg/1000 Cycles	30	30	H-18 Wheel, 1000 g load, ASTM
Compression Set	16 %	16 %	22 hours at RT (Postcured); ASTM
Compression Set, Elevated Temperature	40 %	40 %	22 hours at 158°F (Postcured); ASTM

#### Thermal Properties

Vicat Softening Point	<u>80 °C</u>	176 °F	Rate A; ASTM
Brittleness Temperature	<u>Max -68 °C</u>	Max -90.4 °F	ASTI
Glass Temperature	<u>-46 °C</u>	-50.8 °F	

#### Processing Properties

Processing Temperature	<u>195 °C</u>	383 °F	Ideal melt temp.
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